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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/044,486

01/11/2002

Roger Y. Tsien

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07/08/2004

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EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 07/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------|--------------------------------------|-------------------------------------|--|
| Advisory Action | Application No. 10/044,486 | Applicant(s) TSIEN ET AL. | |
| | Examiner Mark L. Berch | Art Unit 1624 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☒ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See memo.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-4.

Claim(s) withdrawn from consideration: 5-16.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Mark L. Berch
Primary Examiner
Art Unit: 1624

DETAILED ACTION

The amendment filed 6/18/2004 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because: The proposed amendment raises new issues that would require further consideration and/or search. The proposed amendment also presents 9 additional claims without canceling a corresponding number of finally rejected claims.

The replacement of acylthiomethyl with thioacetyl (in both claims and specification) is clearly new matter. The former, as set forth before is Acyl-S-CH₂-, the latter is CH₃C(S)-. These are totally different groups; the former is a substituted methyl compound, in which the methyl is substituted by a sulfur atom which itself substituted by any acyl. The latter is a very specific group, the acetyl group in which the ketonic oxygen is replaced by S. Applicants state that the latter "correctly describes the functional group intended by applicants." But what matters is what the specification as filed had, not what was intended. This can be fixed only by the filing of a CIP.

The material added into paragraph 0050 of the specification appears to be new matter; it's adding some undefined processes to the specification.

Also, applicants removed the definition of n from claim 1, although the variable remains in use.

The amendment to formula (V) would have exchanged one problem for another. There is no such thing as an uncharged -SO₃ group. Such a group would require a sulfur with a valence of VII; that is chemically impossible.

The traverse on "linker" is unpersuasive. All the claim specifies is where it is (it lies between the 3-methylene group and the oxygen atom), and not what it is.

The amendment to paragraph 0050 cannot fix the enablement problem for claim 4. The problem was that the specification does not teach how to use this species, not how to make this species. Paragraph 0050 has only the synthesis of the species, not a teaching of how to use.

The traverse with regard to VI structure is unpersuasive. The one word is noted in paragraph 0053, but that does not convey that the substituent on that position of the moiety is the same substituent as is present on the 7 position of the cephalosporin. The word is simply silent as to the nature of the esterifying group.

The remarks referred to some attachments, but these were not seen.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571)272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1624

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark L. Berch
Primary Examiner
Art Unit 1624

7/2/04